



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

December 22, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 - 06

David L. Huebner
Nancy E. Huebner
Owners
Huebner Farm
W2496 County Road K
Columbus, Wisconsin 53925

Dear Mr. and Mrs. Huebner:

On September 7, 2004, investigators from the Food and Drug Administration (FDA) conducted an inspection at your dairy operation in Columbus, WI. That inspection confirmed that you offered a dairy cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(2)(C)(ii) and § 342(a)(4). You also caused the adulteration of an animal drug because the drug was used in a manner that does not conform to its approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 CFR 530, copy enclosed). This caused the animal drug to be unsafe under Section 512(a) of the Act, 21 U.S.C. § 360b(a), and adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5).

On or about February 2, 2004, you sold a cow, identified with back tag number [redacted] for slaughter as human food through [redacted]. The animal was sold to and slaughtered by [redacted]. Our inspection documented that you use penicillin to medicate animals at your dairy operation. United States Department of Agriculture (USDA) analysis of tissue samples collected from the animal that you sold identified the presence of 0.28 ppm penicillin in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle (21 CFR 556.510, copy enclosed). The presence of this drug in edible tissue from this animal causes the food to be

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adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example, you lack an adequate system for determining the medication status of animals and assuring that animals to which you administer medication have been withheld from slaughter for the appropriate period of time to deplete potentially hazardous residues of drug. Your medication records do not contain the name of the drug administered, the amount of drug administered, the identity of the individual administering the drug, or the pre-slaughter withdrawal times. Food from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4).

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your operations and the foods you distribute are in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action (such as seizure or injunction) without further notice to you.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be held responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your dairy operation into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation that corrections have been made.

Your reply should be sent to Brian D. Garthwaite, Ph.D., Compliance Officer, Food and Drug Administration, Minneapolis District Office, 212 Third Avenue South, Minneapolis, Minnesota 55401.


Our investigators also discussed with you a tissue residue from a cow sold by you on or about June 11, 2003. The USDA analysis of tissue samples collected from that animal identified the presence of 1.066 ppm flunixin in the liver. You received a Food Safety and Inspection Services Violation Notification Letter,

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dated July 29, 2003, regarding the flunixin residue. We recommend that you review with your veterinarian your use of flunixin in your dairy operation. Particularly, we suggest that you review the conditions permitting extralabel use of animal drugs as described in 21 CFR 530.

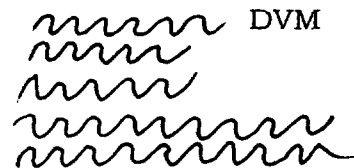
Sincerely,



W. Charles Becoat
Director
Minneapolis District

BDG/ccl 

Enclosures: 21 CFR 530
21 CFR 556.510

xc:  DVM